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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,602	03/01/2002	Matthew Patricelli	063391-0302	7925
30542	7590	08/24/2004	EXAMINER	
FOLEY & LARDNER			COUNTS, GARY W	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	

1641

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/087,602	<b>Applicant(s)</b> PATRICELLI, MATTHEW	
	<b>Examiner</b> Gary W. Counts	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 33-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-32 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/20/02 + 10/17/03</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group VI, claims 21-32 and 48 in the reply filed on July 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 21, 22, 24, 25, 27, 28 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Cravatt et al (US 2002/0045194).

Cravatt et al disclose methods for detecting active proteins in samples (p. 14, para. 0128). Cravatt et al disclose the sample can be a proteome (p. 12). Cravatt et al disclose contacting the sample containing the active proteins with activity based probes (para. 0128). Cravatt et al disclose digesting the sample with a protease to create a mixture of peptides (para. 0128, lines 23, 24). Cravatt et al disclose isolating (separating) peptides covalently tagged with an activity based probe (para. 0128, lines

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24-26). Cravatt et al disclose characterizing the tagged peptides by mass spectrometry and identifying the active proteins by mass spectrometry (para. 0128, lines 27-35).

Cravatt et al disclose that the probe may contain a fluorescent moiety (p. 11, para. 0110).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 21-28, 30-32 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebersold et al. (US 2002/0076739) in view of Cravatt et al (US 2002/0045194).

Aebersold et al disclose an isotope-coded affinity tag (chemical probe) for use in methods of determining target protein abundance between proteomes (complex protein mixtures). Aebersold et al discloses that these chemical probes bind to specific sites of target proteins (p. 2, paragraph 0017). Aebersold et al disclose contacting the

complex protein mixture with the chemical probes (p. 7, col 1, lines 1-14). Aebersold et al disclose digesting the proteins in the sample mixture with proteolyzing agents (p. 7, paragraph 0070). Aebersold et al disclose separating the affinity tagged peptides by affinity isolation procedures (p. 7, paragraph 0071). Aebersold et al disclose analyzing the isolated-tagged peptides (those containing the probe) by liquid chromatography-mass spectrometry or capillary electrophoresis-mass spectrometry (p. 7, paragraph 0072). Aebersold et al disclose the removal of excess affinity tagged reagent (probe) prior to the step of digestion (p. 7, paragraph 0069). Aebersold et al disclose the use of internal standards in the method (p 6).

Aebersold et al differ from the instant invention in failing to teach the probe is an activity based probe.

Cravatt et al disclose probes that have specificity to the active form of proteins (abstract). Cravatt et al disclose that these probes provides for methods for the measurement of specific active proteins in a proteome (p. 12, paragraphs 0116-0018). Cravatt et al disclose that the probe may contain a fluorescent moiety (p. 11, para. 0110). Cravatt et al disclose the use of antibodies to capture ligands comprising a fluorescent moiety (p. 9, paragraph 0095). Cravatt et al disclose that these activity based probes provide for methods of measuring protein activity in proteomics, as opposed to protein abundance (paragraph 0005). Cravatt et al disclose that active target proteins such as enzymes are key to almost every biologic process and that current preteomic approaches are limited to abundance of active target proteins and

that this is a key limitation because the activity of enzymes is often regulated by post-translational modification (paragraph 0005).

It would have been obvious to one of ordinary skill in the art to substitute the activity based probe such as taught by Cravatt et al for the probe of Aebersold et al because Cravatt et al recognized the need for methods of measuring protein activity in proteomics, as opposed to protein abundance (taught by Aebersold et al). Further, Cravatt et al discloses that active target proteins such as enzymes are key to almost every biologic process and that current proteomic approaches are limited to abundance of active target proteins and that this is a key limitation because the activity of enzymes is often regulated by post-translational modification. Therefore, a skilled artisan can have a reasonable expectation of success in incorporating the activity based probes taught by Cravatt et al in the method of Aebersold et al.

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebersold et al and Cravatt et al in view of Little et al (US 2003/0003465).

See above for teachings of Aebersold et al and Cravatt et al.

Aebersold et al and Cravatt et al differ from the instant invention in failing to teach prior to the proteolyzing step, the one or more active target protein bound to the probe are bound to a solid support.

Little et al disclose immobilizing a target polypeptide (protein) to a solid support. Little et al disclose that the target polypeptide (protein) can be immobilized by a streptavidin or avidin to biotin interactions (p. 9, paragraph 073). Little et al disclose that the immobilization of a target polypeptide (protein) provides a means to isolate the

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polypeptide, as well as a means to manipulate the isolated target polypeptide prior to mass spectrometry (p. 3, lines 1-6). Little et al disclose that the term polypeptide and protein are interchangeable (p. 5, paragraph 0045).

It would have been obvious to one of ordinary skill in the art to immobilize the active target protein complex of Aebersold and Cravatt et al to a solid support prior to the proteolysing step because Little et al teaches that the immobilization of a target polypeptide (protein) provides a means to isolate the polypeptide, as well as a means to manipulate the isolated target polypeptide prior to mass spectrometry. Further, Aebersold et al teaches isolating the bound complex from excess probe prior to the proteolyzing step. Therefore a skilled artisan would have a reasonable expectation of success immobilizing the active target protein complex prior to a proteolyzing step.

### ***Conclusion***

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

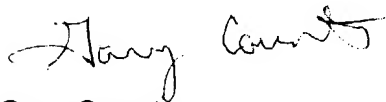
Bogyo et al (US 2002/0150961) provide probes for cysteine hydrolases (active protein) that are useful for profiling cysteine hydrolase activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

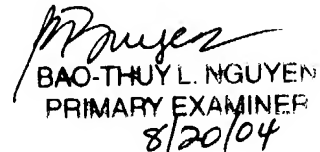
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
August 20, 2004



BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
8/20/04